

K 120313 (1/2)

APR 20 2012

NEO CR Knee System 510(k) Summary

Device Proprietary Name: NEO CR Knee System

Common Name: Total Knee System

Classification regulation: 888.3560

Device Class: Class II

Product Codes: JWH (cemented knees)

Submitter's Name: Pipeline Orthopedics
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Date Summary Prepared: April 17, 2012

Device Description:

The NEO CR Knee System includes components designed for total knee replacement. The system includes femoral components, tibial inserts, tibial trays, patellar components and surgical instrumentation.

The Neo CR Knee System femoral component, when used with the Neo CR articular surfaces, is designed to achieve flexion at high angles and provide a clinical ROM up to 150 degrees.

Intended Use

The Neo CR Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, with an intact posterior cruciate ligament, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, failed partial knee replacement, or failed total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

NEO CR Knee System components are indicated for use only with cement and are single use devices.

NEO CR Knee System 510(k) Summary

Predicate Devices:

The NEO CR Knee System is similar to several predicates including the following.

Trade/Proprietary Name	Manufacturer	510(K) #	Clearance Date
NexGen Complete Knee Solution Cruciate Retaining (CR)-Flex Femoral Components	Zimmer	K023211	10/17/2002
Gender Solutions Natural-Knee Flex System	Zimmer	K073286	03/07/2008
Triathlon Cruciate Retaining (Cr) Total Knee System	Stryker	K040267	5/5/2004

Technological Characteristics:

The metals and standard UHMWPE material from which the components are manufactured are the same materials used in the predicate knee systems and comply with applicable implantable materials standards. A comparison of design features of the NEO CR Knee System to the predicate knee systems and performance testing confirm that the NEO CR Knee System is capable of withstanding the anticipated physiological conditions associated with the indications for use and is substantially equivalent to the predicate devices.

Performance Testing:

The NEO Knee System has been evaluated for tibial tray fatigue strength, insert locking mechanism strength, femorotibial range of motion, femorotibial range of constraint, patellofemoral range of constraint, femorotibial contact areas/contact stress, and patellofemoral contact area and contact stress.

Substantial Equivalence Information:

The NEO CR Knee System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the NEO CR Knee System is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Pipeline Orthopedics, Incorporated
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Ms. Terry Sheridan Powell
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Alexandria, Virginia 22314

APR 20 2012

Re: K120313

Trade/Device Name: NEO CR Knee System

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: January 30, 2012

Received: February 1, 2012

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "For Mark N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120313

Indications for Use Statement

510(k) Number:

~~To be assigned~~

K120313

Device Name:

NEO CR Knee System

Indications for Use: The NEO CR Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, with an intact posterior cruciate ligament, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
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Prescription Use ☒ X

AND/OR


Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120313